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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/616,970	07/11/2003	Satoshi Kidooka	P23559	2858
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GREENBLUM & BERNSTEIN, P.L.C. 1950 ROLAND CLARKE PLACE RESTON, VA 20191			VRETTAKOS, PETER J	
			ART UNIT	PAPER NUMBER
			3739	

DATE MAILED: 08/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/616,970

Applicant(s)

KIDOOKA, SATOSHI

Examiner

Peter J. Vrettakos

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 June 2006.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 7-21 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-5 and 7-21 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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DETAILED ACTION

RCE filed 6-27-06.

Claims 1-5 and 7-21 are rejected below. Claims 1 and 19 are independent.

The action is non-final.

To facilitate readability of the Office Action, all new arguments are in bold.

New art (Schmaltz et al. 6,050,996) is presented to show RF electrodes mounted on forceps jaws/manipulation members as implied in Marucci et al. (6,582,451).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 7,9,10, 11, 13-15 and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marucci et al. (6,582,451) **in view of Schmaltz et al. (6,050,996).**

Marucci neglects to expressly disclose manipulation members comprising electrodes.

Independent claims 1,19 (parentheticals refer to Marucci)

A treatment tool (see figure 1a – *the rejection relies heavily upon this figure*) to be inserted into a human body through an endoscope (col. 1:20-25) comprising:

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an elongated inserting portion (13) to be inserted through an accessory channel of the endoscope;

a supporting member (11) attached to a distal end of said inserting portion, said supporting member being provided with a slit (depicted at 74 in figure 1a);

a shaft (28, better depicted but not enumerated in figure 1c) attached (through the holes adjacent element 74 in figure 1a) to said supporting member so as to cross said slit in a width direction thereof (depicted figure 1b);

a pair of manipulation members (12, 12) at least one of said pair of manipulation members being pivotably supported by said shaft within said slit (depicted in figure 1g, *inter alia*) so as to open and close with respect to another of said pair of manipulation members like a pair of pincers ("jaws"), said pair of manipulation members comprising a pair of electrodes (*see col. 6:33-40 for a disclosure of jaw members and associated modalities strongly related to electrode use such as radiofrequency and unipolar/bipolar electrocautery*); and

a spacer (constituted by elements 24-25) located between said pair of manipulation members,

wherein said shaft (28) is supported by said spacer (24-25) so as not to come off from said supporting member.

19. (New) A treatment tool configured to be inserted into a human body through an endoscope (col. 1:20-25), said treatment tool comprising: an elongated insertion portion configured to be inserted through an accessory channel of the endoscope;

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a supporting member (11) attached to a distal end of said inserting portion, said supporting member having a longitudinally extending slit (74);

a shaft (28) attached to said supporting member so as to extend across said slit in a width-wide direction;

a manipulation member (12), pivotally supported (see cross hairs at 28 in figure 3e) by said shaft so as to pivot about said shaft between opened (figure 1e) and closed (figure 1g) positions with respect to another manipulation member; and

a spacer (24-25) fixedly positioned with respect to said supported member within said slit (74), said spacer located between said manipulation member and said another manipulation member (two element 12s) and supporting said shaft (28).

Schmaltz et al. discloses analogous forceps (10) with jaws/manipulation members (19,20) with RF electrodes (11,12).

Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify Marucci in view of Schmaltz by including as a design expedient jaw/manipulation members (Marucci 12) comprising electrodes (Schmaltz 11,12) in light of the disclosure in Marucci col. 6:33-40 where RF and electrocautery are disclosed. The motivation would be to create a device capable of performing through electrodes its disclosed (in Marucci) intended use (RF, electrocautery).

Dependent claims

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2. The treatment tool according to claim 1, wherein said shaft (28) is pressed (depicted in figure 1e) into said spacer (24-25). Note the corresponding hole into which element 28 rests is depicted but not enumerated figure 1b).

3. The treatment tool according to claim 2, wherein said spacer (24-25) is provided with a through hole (depicted and enumerated –28- in figure 1a) having an inner diameter smaller than an outer diameter of said shaft (inherent for shaft to rest securely in through hole), said shaft being pressed (again, inherent) into said through hole.

4. The treatment tool according to claim 1, comprising a pair of said shafts (28 and 26 – figure 1a), both of said shafts being pressed into said spacer (24-25), each of said pair of manipulation members (12) being pivotably mounted to respective one of said shafts so as to open and close like a pair of pincers (“jaws”).

5. The treatment tool according to claim 4, wherein said spacer (24-25) is provided with a pair of through holes (figure 1a, element 28 and the non-enumerated proximal and longitudinally parallel hole) formed in parallel to each other, each of said through holes having an inner diameter smaller than an outer diameter of each of said shafts (26,28) (inherent for shaft to rest securely in through hole), said shafts being pressed (again, inherent) into respective one of said through holes.

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7. The treatment tool according to claim 6, wherein said spacer is made of poly-tetra-fluoro-ethylene. See col. 12:35-41. The disclosure of atraumatic plastic anticipates poly-tetra-fluoro-ethylene, an atraumatic plastic.

9. The treatment tool according to claim 6, wherein said manipulation members (12; “jaws”) are connectable to a high frequency power supply. See col. 6:33-40 for a disclosure of jaw members and associated modalities strongly related to connections to high frequency power supplies such as unipolar/bipolar electrocautery.

10. The treatment tool according to claim 1, wherein said supporting member (11) is made of insulating material. See col. 12:35-41 – plastic = insulating material.

11. The treatment tool according to claim 10, wherein said supporting member (11) is made of rigid plastic. See col. 12:35-41.

13. (New) The treatment tool according to claim 1, wherein said shaft (28) engages said supporting member (11), said spacer (24,25) and one of said manipulation members (12). See figure 1g.

14. (New) The treatment tool according to claim 1, wherein said pair of manipulation members are configured to rotate (see cross hairs at 28 in figure 3e inferring pivot/rotation) about said shaft.

15. (New) The treatment tool according to claim 1, wherein said spacer is fixedly positioned with respect to said supporting member. Addressed below in Response to Arguments section.

20. (New) The treatment tool according to claim 19, said manipulation member and said another manipulation member comprising conductive electrodes. Addressed above in part of rejection toward claim 1.

Claims 8 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marucci et al. in view of Mayenberger (5,853,412).

Marucci is silent concerning ceramics.

Mayenberger discloses in an invention analogous to Marucci, ceramic parts (insulating by design). See Mayenberger claims 5 and 8.

Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify Marucci in view of Mayenberger by including as a design expedient ceramic parts for their insulating properties (motivation) as disclosed in Mayenberger.

Response to Arguments

The prior 35 USC §112 rejections are obviated. The Applicant has pointed out where in the specification support for prior rejected claims is found. The Applicant has also amended claims to more clearly define the claimed subject matter.

Applicant's arguments filed 6-27-06 have been fully considered but they are not persuasive. Applicant argues that Marucci jaw members/manipulation members are platforms for electrodes and as a result do not "comprise" electrodes. In response the Office directs the reader to MPEP 2111.03 [R-3] regarding the word, "comprising". The MPEP evinces that "comprising" is open-ended and "does not exclude additional, unrecited elements." To this end, Marucci disclosing in col. 6:33-40 that jaw members are platforms for electrodes does not invalidate the Examiner's designation that Marucci's jaw members **include** electrodes. (The Office contends that jaw members acting as platforms for electrodes (with electrodes included in the description) is equivalent to jaw members comprised of electrodes, and implicitly additional, unrecited elements such as a platform.) **Further, in response to the Applicant's arguments the MPEP reference above indeed guides this analysis for claimed subject matter, as the phrase "manipulation members comprising a pair of electrodes" is in the Applicant's claim 1 inviting the broad apprehension. Is the Applicant arguing that "comprising" in everyday usage does not warrant the same open-ended definition as when it is in a claim?**

The argument that there is a significant difference between manipulation members/jaws comprising (potentially amongst other elements) electrodes and

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manipulation members/jaws acting as platforms for therapeutic modalities that infer electrodes is semantical. Marucci discloses manipulation members/jaws on which RF or electrocautery (electrodes are necessary for both modalities) can potentially be performed. This at the very least makes obvious the Applicant's claims that read, "a pair of manipulation members...comprising a pair of electrodes." Whether the prior art discloses manipulation members as a platform for electrodes or manipulation members with electrodes is not patentably dispositive.

Next, the Applicant argues that the Marucci spacer (24-25) is not necessarily disclosed as insulating (as would be implied by disclosure of "atraumatic plastic"). The Applicant refers to col. 12:36-41 and mentions that this broad disclosure is merely an invitation to invent. The Office has already in response changed the prior Marucci 35 USC § 102 rejection to a 35 USC § 103 rejection. The disclosure in col. 12:36-41 is broad, however, the Office strongly asserts that because the disclosure only permits a limited number of variations one of ordinary skill in the art would deduce from that disclosure that the Marucci spacer could be made of plastic (hence insulating) and that any benefits would be determined through routine experimentation. **Further, the Applicant is directed to MPEP § 2144.05 II.A.**

A. Optimization Within Prior Art Conditions or Through Routine Experimentation

Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be *prima facie* obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); see also *Peterson*, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.");

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In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.). For more recent cases applying this principle, see *Merck & Co. Inc. v. Biocraft Laboratories Inc.*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), *cert. denied*, 493 U.S. 975 (1989); *In re Kulling*, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997).

This section of the MPEP includes case law alleging that when general conditions are disclosed in the prior art, an artisan is armed with the normal desire to improve upon (modify) what is already known providing *motivation* to determine optimal combinations through routine experimentation. In the instant case, the prior art (Marucci) discloses general conditions (a spacer that could potentially be made of plastic). The Office asserts that, consistent with the above case law, an artisan would be motivated by a normal desire to determine if a plastic spacer was optimal in Marucci, and would then determine if a plastic spacer was optimal through routine experimentation, *thereby making obvious the Applicant's plastic spacer*. To argue otherwise, would involve inappropriately viewing the Marucci patent in a vacuum.

Contrary to the Applicant's arguments, if electrodes were placed on the jaws (12) of Marucci as strongly inferred in col. 6:33-40, the spacer (24,25) would not be required to be electrically conductive. The prior art is replete (6,776,780 Mulier et al., see depicted wires 56 and 58, also see col. 1:61-62; also see 6,050,996 Schmaltz et al. wiring disclosure in the Abstract) with electrodes on jaws with insulated wiring that runs along a shaft and to the electrode at the device distal end without an electrically conductive spacer. There is absolutely no requirement that if an artisan were to adhere to Marucci's suggestive disclosure

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of radiofrequency treatment or electrocautery treatment (by placing electrodes on the jaws) that the artisan would be restricted to making the spacer (24,25) electrically conductive.

Also, the Applicant argues that the Marucci jaws (12) do not pivot about the shaft (28). The Office responds that the jaws (12) in fig. 1e (open position) and then fig. 1g (closed position) do indeed pivot around shaft (28) *through linkage 25*. See the cross hairs in figure 1g at element 28 inferring a pivot point. **The Applicant has reasserted 6-27-06 his apprehension of the claim language, and the Examiner in turn reasserts his apprehension of the claim language. There is simply no current claim language that precludes the Examiner's apprehension of the claim language.**

The Applicant argues that the Marucci spacer (24-25) is not fixedly positioned with respect to the support member (11). The Office respectfully disagrees. Figure 1a shows a distal hole in support member (11) through which the spacer (24-25) is fixedly positioned with respect to the support member by shaft 28. (The spacer's articulation in space does not preclude this designation/apprehension.) **The Applicant has reasserted 6-27-06 his apprehension of the claim language, and the Examiner in turn reasserts his apprehension of the claim language. There is simply no current claim language that precludes the Examiner's apprehension of the claim language.**

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

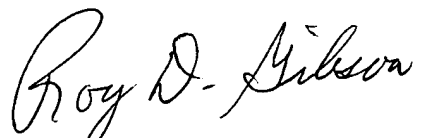
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J. Vrettakos whose telephone number is 571-272-4775. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pete Vrettakos
August 5, 2006




ROY D. GIBSON
PRIMARY EXAMINER